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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,007	07/24/2003	Robert Ginsburg	RADNT-008G3	9911

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EXAMINER	
NASSER, ROBERT L	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,007	GINSBURG ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 50-94 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 50-94 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 20030724.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 64-84 rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1-24 of prior U.S. Patent No. 6527798. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 64-84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-73 of U.S. Patent No. 6497421. Although the conflicting claims are not identical, they are not patentably

distinct from each other because the patented claims are a method of using the device of these claims, and as such, the inventions cover common subject matter, as it would have been obvious to use the device of the current claims in the recited method.

Claims 50-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-73 of U.S. Patent No. 6497721 in view of Ginsburg 5486208. The patented claim lack the heat exchange fins, which are taught to be obvious by the previous Ginsburg patent.

Claims 88-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-30 of U.S. Patent No. 6527798 in view of Panyard et al. Panyard showed a thermal control system that allowed the user to set a desired target temperature and sensed body temperature to control the supply of fluid relative to the target temperature. While the system of Panyard is not a catheter, it is a heating/cooling system and the supply system was identical to that of the previous invention. From this teaching, it would have been obvious to modify the previous invention to use such a control system to ensure precise control of the patient's condition.

Claims 64-84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6620188. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are broader versions of the patented claims, and, as such, are covered by the patented claims.

Claims 50-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-73 of U.S. Patent No. 6620188 in view of Ginsburg 5486208. The patented claim lack the heat exchange fins, which are taught to be obvious by the previous Ginsburg patent.

Claims 88-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of U.S. Patent No. 6635076 in view of Ginsburg 5486208. The patented claim lack the heat exchange fins, which are taught to be obvious by the previous Ginsburg patent.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-57, 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Saab 5624392. Saab shows a heat exchange catheter system including an elongate flexible catheter having a proximal and distal end, where the catheter has a distal insertion portion including balloon 72 or 236, where the balloon has ribs on its exterior 244, 246, or 252, where in figure 6, the ribs are annular and helical. The device further has a working lumen 11, which contains a guidewire therein (see column 8, lines 3-4). There is a fluid circulated through the balloon the effect heat exchange. With respect to claim 51, the balloon of figure 7 has a plurality of lobes. With respect to claim 57, 60, and 62 in column 14, lines 61-67, Saab teaches using the device to deliver medication

or a medical device including a therapeutic device. As such, it is inherent that there be a device for infusing the medicine.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 58, 59, 61, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab. Applicant has not selected the specific devices listed for a specific reason and applicant has not stated that their selection solves a stated problem. Therefore, the exact medical device used with Saab's device would have been a mere matter of design choice for one skilled in the art.

Claims 88-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab 5624392 in view of Panyard 5755755. Saab does not teach the recited control system. Panyard showed a thermal control system that allowed the user to set a desired target temperature and sensed body temperature to control the supply of fluid relative to the target temperature. While the system of Panyard is not a catheter, it is a

heating/cooling system and the supply system was identical to that of Saab. From this teaching, it would have been obvious to modify Saab to use such a control system to ensure precise control of the patient's condition.

Claims 64-87 would be allowable if the double patenting rejection were overcome. Claims 64-84 define over the art, in that none of the art shows the blood flow channeling sleeve, as recite in that claim. The examiner notes that tubes 244 or 246 of Saab might be considered a channeling sleeve, but they are closed at one end and therefore not capable of channeling blood. Claims 85-87 define over the art of record in that none of the art shows a heat exchanger, as claimed, with 2 curved surfaces, each with a different thermal transmissivity.

Claims 93 and 94 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims paragraph and if the double patenting rejection were overcome

Claims 93-94 define over the art in that none of the art shows a plurality of catheter devices, in combination with claim 88, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
June 14, 2004

ROBERT L. NASSER
PRIMARY EXAMINER

ROBERT L. NASSER
PRIMARY EXAMINER